

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC
REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO

Civil Action No.: 2:15-cv-
08736 _____

S u s a n H o l m a n

Name of Plaintiff

PLAINTIFF FACT SHEET

Each plaintiff who allegedly suffered injury as a result of a pelvic mesh product manufactured or sold by Ethicon, Inc. must complete this Plaintiff Fact Sheet. In completing this Fact Sheet, you are under oath and must answer every question and provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can and then state that your answer is incomplete and explain why as appropriate. If you select an "I Don't Know" answer, please state all that you do know about that subject. If any information you need to complete any part of the Fact Sheet is in the possession of your attorney, please consult with your attorney so that you can fully and accurately respond to the questions set out below. If you are completing the Fact Sheet for someone who cannot complete the Fact sheet herself, please answer as completely as you can.

The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. The questions and requests for production contained in the Fact Sheet are non-objectionable and shall be answered without objection. This Fact Sheet shall not preclude Defendants from seeking additional documents and information on a reasonable, case-by-case basis pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order.

In filling out this form, please use the following definition: "healthcare provider" means any doctor, physician, surgeon, pharmacist, hospital, clinic, center, physician's office, infirmary, medical or diagnostic laboratory, or other facility that provides medical care or advice, and any pharmacy, x-ray department, radiology department, laboratory, physical therapist or physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in the diagnosis, care and/or treatment of you.

In filling out this form, the terms "You" or "Your" refer to the person who received pelvic mesh product(s) manufactured or sold by Ethicon, Inc. and who is identified in Question I.1 (a) below.

To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary.

I. BACKGROUND INFORMATION

- 1) Please state:
 - a. Full name of the person who received the pelvic mesh product(s), including maiden name:
Susan Holman, maiden name Susan Stevens
 - b. Full name of the person completing this form, if different from the person listed in 1 (a) above, and the relationship of the person completing this form to the person listed in 1 (a) above: Brock P. Alvarado, attorney for Susan Holman
 - c. The name and address of your primary attorney: Brock P. Alvarado, 1524 W. 96th Avenue, Crown Point, IN 46307
- 2) Your Social Security Number: 317-60-8801
- 3) Your date of birth: 07/25/1955
- 4) Your current residence address: 587 E. 116th Court, Crown Point, IN 46307

If you have lived at this address for less than 10 years, provide each of your prior residence addresses from 2000 to the present:

Prior Address	Dates You Lived At This Address
6522 Colorado Avenue, Hammond, IN 46232	1984- 2012
3980 Kingsway Dr., Crown Point, IN 46307	2012-2017

5) Have you ever been married? Yes x No

If yes, provide the names and addresses of each spouse and the inclusive dates of your marriage to each person.

Rick Weaver, address unknown, May 1971-May 1978

Phillip Holman, 6522 Colorado Avenue, Hammond IN 46232, May 1978-December 2016

6) Do you have children? Yes x No

If Yes, please provide the following information with respect to each child:

Full Name of Child	Date of Birth	Home Address (if different from yours)	Whether Biological/Adopted
Tammy Weaver	10/9/71	Camelot Drive, Portage, Indiana	biological
Elizabeth Weaver	11/10/73	587 E. 116 th Court, Crown Point, IN 46307	biological
Tabitha Hollaway	3/18/79	3980 Kingsway Drive, Crown Point, IN 46307	biological
Kristen Holman	6/27/82	587 E. 116 th Court, Crown Point, IN 46307	biological

7) Identify the name and age of any person who currently resides with you and their relationship to you:

Elizabeth Weaver DOB 11/10/73, Kristen Holman DOB 6/27/82, Isaac Holman DOB 8/9/03 and Sierra Holman DOB 2/6/03.

8) Identify all secondary and post-secondary schools you attended, starting with high school and please provide the following information with respect to each: N/A.

Name of School	Address	Dates of Attendance	Degree Awarded	Major or Primary Field
8 th grade education				

- 9) Please provide the following information for your employment history over the past 10 years up until the present:

Employer Name	Addresses	Job Title/ Description of Duties	Dates of Employment	Salary/Rate of Pay
On disability since 1994. Last worked at a wallpaper plant in Hammond Indiana.				

- 10) Have you ever served in any branch of the military? Yes ___ No **x**___

If Yes, please provide the following information: N/A

- a. Branch and dates of service, rank upon discharge and the type of discharge you received: _____

- b. Were you discharged from the military at any time for any reason relating to your medical, physical, or psychiatric condition? Yes ___ No ___

If Yes, state what that condition was: N/A

- 11) Within the last ten years, have you been convicted of, or plead guilty to, a felony and/or crime of fraud or dishonesty? **Yes** ___ **No** **x**

If Yes, please set forth where, when and the felony and/or crime:

II. CLAIM INFORMATION

- 12) Please complete the following chart for each implanted Ethicon, Inc. pelvic mesh product. Insert additional lines as necessary.

Pelvic Mesh Product and lot number (if sticker affixed, so indicate)	Date and Location of Implant	Reason for Implant	Implanting Doctor and Address
<u>Product No. 1:</u>			
Ethicon TVT Obturator System	11/11/04 Community Hospital 901 MacArthur Boulevard, Munster IN 46321	urinary stress incontinence	Dr Gregory Bales 5841 S Maryland Ave, Chicago, IL 60637 Dr. Howard Diamond, deceased approx 2010
<u>Product No. 2:</u>			
<u>Product No. 3:</u>			

- 13) For each pelvic mesh product identified above, describe your understanding of the medical condition for which you received the pelvic mesh product(s): urinary stress incontinence_____
- 14) For each Ethicon, Inc. pelvic mesh product identified above, indicate if, prior to implantation, you received any written and/or verbal information or instructions, including any risks or complications that might be associated with the use of the product(s)? **Yes** ___ **No** **x** ___ **Don't Know** ___

If Yes: N/A

- a. Provide the date you received the written and/or verbal information or instructions:

- b. Identify by name and address the person(s) who provided the information or instructions: _____

c. What information or instructions did you receive? _____

d. If you have copies of the written information or instructions you received, please attach copies to your response.

15) For each Ethicon, Inc. pelvic mesh product(s) that remains implanted in you:

a. Has any doctor recommended removal of the pelvic mesh product(s)?
Yes x No

If Yes, Identify by name and address the doctor who recommended removal and state your understanding of why the doctor recommended removal:

On 1/24/12 Dr. Bales performed revision of sling and insertion of new AMS American Medical Systems MiniArc sling to try and cure the failure of and conditions caused by the Ethicon product.

16) Have any of the Ethicon, Inc., pelvic mesh product(s) been removed, in whole or in part?

Yes x No Don't Know

If Yes, for each pelvic mesh product removed provide:

a. On what date, where and by whom (doctor) was the pelvic mesh product(s), or any portion of it, removed? See above answer to #15.

b. Explain why you consented to have the pelvic mesh product(s), or any portion of it, removed? Plaintiff wanted to stop her continuing and worsening incontinence and pain caused by the Ethicon product.

c. Does any medical treater, physician or anybody else on your behalf have possession of any portion of the pelvic mesh product® that was previously implanted in you and removed? Yes No Don't Know x

If Yes, please state name and address of the person or entity having possession of same. Dr. Gregory Bales would be the only person possible since he explanted the product from me in 2012.

- 17) Do you claim that you suffered bodily injuries as a result of the implantation of any Ethicon, Inc., pelvic mesh product(s)? Yes x No

If Yes:

- a. Describe the bodily injuries, including any emotional or psychological injuries, that you claim resulted from the implantation of the pelvic mesh product(s).

Vaginal and abdominal/stomach pain, urinary problems, incontinence, and leaking, dyspareunia, urethrocele, indented urethra, increased risk of cognitive and functional decline due to extra exposure to general anesthesia necessitated by revision/explantation surgery, and subsequent development of belly button hernia and diabetes, as well as, depression from the foregoing.

- b. When is the first time you experienced symptoms of any of the bodily injuries you claim in your lawsuit to have resulted from the pelvic mesh product(s)?

After the 2004 implantation after the 2012 revision/explantation and re-implantation procedures.

- c. When did you first attribute these bodily injuries to the pelvic mesh product(s)?

After the 2004 implantation and after the 2012 revision/explantation and re-implantation procedures.

- d. To the best of your knowledge and recollection, please state approximately when you first saw a health care provider for each of those bodily injuries you claim to have experienced relating to the pelvic mesh product(s):

After the 2004 implantation and after the 2012 revision/explantation and re-implantation procedures.

- e. Are you currently experiencing symptoms related to your claimed bodily injuries? Yes x No

If Yes, please describe your current symptoms in detail

Vaginal and abdominal/stomach pain, urinary problems, incontinence, and leaking, dyspareunia, urethrocele, indented urethra, increased risk of cognitive and functional decline due to extra exposure to general anesthesia necessitated by revision/explantation surgery, and subsequent development of belly button hernia and diabetes, as well as, depression from the foregoing. The episodes of stomach and vaginal area pain occur 3-4 times a week and are increasing. Plaintiff has had a catheter with bag for the past 3 years to control incontinence Plaintiff had botox treatment 3 years ago with no real effect. Plaintiff wears urinary pads for sitting and sleeping and such pads cause sores and skin irritation to her private areas.

- f. Are you currently seeing, or have you ever seen a doctor or healthcare provider for each of the bodily injuries or symptoms listed above? Yes x No

If Yes, please list all doctors you have seen for treatment of any of the bodily injuries you have listed above.

Provider Name and Address	Condition Treated	Approximate Dates of Treatment
Gregory Bales 5841 S Maryland Ave, Chicago, IL 60637	Symptoms described above in #17e.	2004 to present. Plaintiff sees Dr. Bales every 6-7 weeks for catheter change in a Munster, Indiana clinic on Calumet Avenue.
Steven Corse 3741 45th St, Highland, IN 46322	general conditions, family practice, diabetes management.	prn

- g. Were you hospitalized at any time for the bodily injuries you listed above? Yes No x other than the previously noted implantation explantation surgeries in 2004 and 2012.

If Yes, please provide the following: N/A

Hospital Name and Address	Condition Treated	Approximate Dates of Treatment

- 18) Other than the Ethicon, Inc. pelvic mesh product(s) that are the subject of your lawsuit, have you been implanted with any other pelvic mesh products? Yes ☒ No ☐

If Yes, please provide the following information:

a. Product Name(s): On 1/24/12 Dr. Bales performed revision of sling and insertion of new AMS American Medical Systems MiniArc sling to try and cure the failure of and conditions caused by the Ethicon product.

b. Date of implantation procedure(s) and name and address of implanting doctor(s):

On 1/24/12 Dr. Bales performed revision of sling and insertion of new AMS American Medical Systems MiniArc sling to try and cure the failure of and conditions caused by the Ethicon product.

c. Condition(s) sought to be treated through placement of the device(s):
Failure of Ethicon TVT Obturator System and resulting aforementioned harm.

d. Whether the product(s) remain implanted inside of you today?
Yes ☒ No ☐

- 19) Are you making a claim for lost wages or lost earning capacity?

Yes ☐ No ☒

If Yes, state the annual gross income you derived from your employment for each year, beginning five years prior to the implantation of the pelvic mesh product(s) until the present: N?A

- 20) Are you making a claim for lost out-of-pocket expenses?

Yes ☐ No ☐ Plaintiff is not yet sure.

If Yes, please identify and itemize all out-of-pocket expenses you have incurred:

- 21) Has anyone filed a loss of consortium claim in connection with your lawsuit regarding the pelvic mesh product(s)?

Yes ___ No x

If Yes, identify by name and address the person who filed the loss of consortium claim, state the relationship of that person to you, and state the nature of the claim: **N/A**.

- 22) Please indicate whether the consortium plaintiff is alleging any of the claimed damages set forth below and itemize the alleged damages/expenses: **N/A**.

Claims	Yes/ No	Itemized Damages/Expenses
Loss of services of spouse		Not applicable
Impaired sexual relations		Not applicable
Lost wages/ lost earning capacity		
Lost out-of-pocket expenses		
Physical injuries		Not applicable
Psychological Injuries/ Emotional Injuries		Not applicable
Other		Not applicable

- 23) Please list the name and address of any healthcare providers the consortium plaintiff has seen for treatment for any physical, emotional, or psychological injuries or symptoms alleged to be related to the loss of consortium claim. **N/A.**
- 24) Have you or anyone acting on your behalf had any communication, oral or written, with any of the defendants or their representatives, other than your attorneys?

No x

If Yes, set forth the date of the communication, the method of communication, the name of the person with whom you communicated, and the substance of the communication between you and any defendants or their representatives: **N/A**

III. MEDICAL BACKGROUND

- 1) Provide your current age: 62 Height 5'5" Weight 271
- 2) At the time you received each pelvic mesh product(s), please state:

Your age approximately 49 and approximately 57. Your approximate weight unknown

- 3) State number of vaginal births you have had? 4
- 4) State the number of cesarean section births you have had? 0
- 5) In chronological order, list any and all surgeries, procedures, or hospitalizations you had in the 10 year period **BEFORE** implantation of the pelvic mesh product(s); identifying by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and providing the approximate date(s) for each. Insert additional rows as necessary.

In the 10 year period before implantation in 2004 plaintiff does not believe she had surgery.

Doctor or Healthcare Provider Involved (including address)	Description of Surgery Hospitalization	Approximate Date
To the best of her belief and recollection plaintiff believes not applicable.		

- 6) In chronological order, list any and all surgeries, procedures, or hospitalizations you had **AFTER** the implantation of the pelvic mesh product(s); identifying by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each. Insert additional rows as necessary.

Doctor or Healthcare Provider Involved (including address)	Description of Surgery/ Hospitalization	Approximate Date
St. Margaret Hospital, Hammond Indiana	double knee replacement surgeries.	2005
Previously identified Dr. Gregory Bales	Aforementioned revision explantation surgery of Ethicon product.	2012

- 7) To the extent not already provided in the charts above, provide the name, address, and telephone number of every doctor, hospital, or other health care provider from which you have received medical advice and/or treatment for the past **10 years**. Insert additional rows as necessary. See above charts.

[illegible]

- 8) Please describe your physical activities associated with daily living, physical fitness, household tasks, and employment-related activities *before* the implantation of each pelvic mesh product.

Before implantation plaintiff performed all necessary activities of daily living aside from urinary stress incontinence.

- 9) Please describe your physical activities associated with daily living, physical fitness, household tasks, and employment-related activities *after* the implantation of the pelvic mesh product(s).

After implantation plaintiff has experienced vaginal and abdominal/stomach pain, urinary problems, incontinence, and leaking, dyspareunia, urethrocele, indented urethra, increased risk of cognitive and functional decline due to extra exposure to general anesthesia necessitated by revision/explanation surgery, and subsequent development of belly button hernia and diabetes, as well as, depression from the foregoing. The episodes of stomach and vaginal area pain occur 3-4 times a week and are increasing. Plaintiff has had a catheter with bag for the past 3 years to control incontinence Plaintiff had botox treatment 3 years ago with no real effect. Plaintiff wears urinary pads for sitting and sleeping and such pads cause sores and skin irritation to her private areas.

10) To the best of your knowledge, have you suffered from any of the following:

Medical Condition	Yes _____ No <input checked="" type="checkbox"/> _____	Sought treatment for? Yes _____ No _____	Indicate whether condition occurred pre-implant, post-implant or both (explain, if necessary) Pre _____ Post _____
Adhesions	Yes _____ No <input checked="" type="checkbox"/> _____	Yes _____ No _____	Pre _____ Post _____
Bleeding or Clotting Disorders	Yes _____ No _____	Yes _____ No _____	Pre _____ Post _____
If Yes, please specify disorder:	Yes _____ No _____	Yes _____ No _____	Pre _____ Post _____
Bowel Obstruction	Yes _____ No <input checked="" type="checkbox"/> _____	Yes _____ No _____	Pre _____ Post _____
Bowel Perforation	Yes _____ No <input checked="" type="checkbox"/> _____	Yes _____ No _____	Pre _____ Post _____
Cancer	Yes _____ No <input checked="" type="checkbox"/> _____	Yes _____ No _____	Pre _____ Post _____
If Yes, please specify type:	Yes _____ No _____	Yes _____ No _____	Pre _____ Post _____
Chronic Constipation	Yes _____ No <input checked="" type="checkbox"/> _____	Yes _____ No _____	Pre _____ Post _____
Collagen Disorder/Deficiency	Yes _____ No <input checked="" type="checkbox"/> _____	Yes _____ No _____	Pre _____ Post _____

63435-1402658
 COMMUNITY HOSPITAL
 901 MacArthur Boulevard
 Munster, In 46321-2959

HOLMAN, SUSAN
 ACCT: 1402658 ROOM: 3S 344 2
 MR#: 063-435 PTYP: OP-SURGERY
 DOB: 7/25/55 ISSUED: 11/13/04
 PAGE 1

COPY

ORDER # ORDER DATE/TIME RESULT DATE/TIME
 4199047 11/12/04 10:45 11/12/04 10:45

Dictated by: DIAMOND, MD HOWARD M

OPERATIVE REPORT

DATE OF SURGERY: 11/11/2004

PREOPERATIVE DIAGNOSIS: 1. ANATOMICAL URINARY STRESS INCONTINENCE.
 2. CYSTOCELE.

POSTOPERATIVE DIAGNOSIS: 1. ANATOMICAL URINARY STRESS INCONTINENCE.
 2. CYSTOCELE.

PROCEDURE PERFORMED: A TRANSVAGINAL TAPE SLING PROCEDURE (OBTURATOR APPROACH).

SURGEON: DR. G. BALES AND DR. H. DIAMOND.

ANESTHESIA: GENERAL ENDOTRACHEAL.

TECHNIQUE: On 11/11/2004, the patient was taken to the operating room. After the induction of an uneventful general endotracheal anesthesia, she was prepped and draped in a modified dorsal lithotomy position. The patient was given Ancef 1 gram intravenous Piggyback before surgery started. An 18 French Foley catheter was introduced into the bladder. We had no trouble therefore identifying the bladder neck.

A small vertical incision was made over the area of the mid urethra. Then, the vaginal flaps were dissected using Metzenbaum scissors. We were able to bring the Metzenbaum scissors right to the inferior pubic ramus and then slide it right along the bone right into the endopelvic fascia through the obturator fascia. This of course was done on both sides. Using the Ethicon TVT obturator system, a wing guide was then placed in the area and then the needle guide was placed over the wing guard through the obturator fascia and then the wing guard was removed. We then of course had rotated following just under the bone, torqued and rotated the needle to bring it out just in the skin fold. A small skin incision was made there in order to bring the needle through the skin. This was done of course on both sides. We then lifted up the mesh tape in order to just make it just slightly snug on the urethra at the mid point but not too tight and this was of course done using a mosquito under the tape to make sure we were not putting too much compression at the mid urethral site. Once we felt comfortable in terms of the tension on the tape, the plastic sheathing was removed. The excess tape cut at both sites where it came out through the skin. The vaginal mucosa was then closed using 3-0 Vicryl. The sites where the tape had been perforated through the skin with the obturator needles was then closed using Derma-Bond skin glue.

At the end of the case the Foley catheter was removed with the hope that the

Community Healthcare System



MOB CSC SAME DAY SURG
Inpatient Record

HOLMAN, SUSAN
MRN: 10081729
DOB: 7/25/1955, Sex: F
Adm: 1/24/2012, D/C: 1/24/2012

Pre-Procedure Instructions (continued)

Signed by Sharon Jukes on 1/18/2012 10:11 AM

Operative Notes

OP Notes by Lisa Chase, RN at 1/24/2012 2:53 PM

Version 1 of 1

Author: Lisa Chase, RN
Filed: 1/24/2012 2:55 PM
Editor: Lisa Chase, RN (Registered Nurse)

Service: (none)
Note Time: 1/24/2012 2:53 PM

Author Type: Registered Nurse
Status: Signed

FOLEY CATHETER INTACT EMPTIED 150CC BLUES URINE, DR BALES WAS HERE TO SEE PT AND AWARE OF OUTPUT, PT THEN HAD AN ADDITIONAL 50 CC CLEAR YELLOW URINE OUT. VITALS STABLE, PT TO PUSH FLUIDS AT HOME, IF PT HAS ANY QUESTIONS OR CONCERNS SHE IS TO CALL DR BALES.

Signed by Lisa Chase, RN on 1/24/2012 2:55 PM

OP Notes signed by Gregory T. Bales, MD at 1/25/2012 12:06 PM

Version 1 of 1

Author: Gregory T. Bales, MD
Filed: 1/25/2012 12:06 PM
Editor: Gregory T. Bales, MD (Physician)

Service: (none)
Note Time: 1/24/2012 11:11 PM

Author Type: Physician
Status: Signed

Date of Procedure: 01/24/2012

PREOPERATIVE DIAGNOSIS:
Urinary incontinence (788.3).

POSTOPERATIVE DIAGNOSIS:
Urinary incontinence (788.3).

PROCEDURE PERFORMED:
Complete urodynamic study (51726, 51741, 51795, 51797, 51785).
Revision of sling (57287).
Insertion of new MiniArc sling (57288).
Cystoscopy (52000).

SURGEON:
Gregory Bales, M.D.

ASSISTANT:
Pauline Fedunok, P.A.

ANESTHESIA:
Local, followed by general.

INDICATIONS:
The patient is a very pleasant, 56-year-old woman who has been having problems with her urinary control. She had undergone a urethral sling procedure by Dr. Howard Diamond about five years ago. This had helped a little although the patient, over the last little while, has noted that her urinary control has again worsened. She has obvious stress incontinence on evaluation. The patient also has symptoms of urgency. The patient understands she is undergoing an urodynamic study to better define her urinary parameters and then very likely might need another sling. The